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10/018,470	11/21/2002	Claire Marie Fraser	CHIR-0319	2853

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PO Box 8097
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EXAMINER

NEGIN, RUSSELL SCOTT

ART UNIT	PAPER NUMBER
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1631

MAIL DATE	DELIVERY MODE
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09/26/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/018,470

Applicant(s)

FRASER ET AL.

Examiner

Russell S. Negin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 24-81 is/are pending in the application.
- 4a) Of the above claim(s) 3-21 and 24-81 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 9 July 2007 has been entered.

Comments

Claims 1-21 and 24-81 are pending and claims 1-2 are examined in this Office action.

Claim Rejections - 35 USC § 101

The following rejection is newly applied:

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1 and 2 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The following analysis of facts of this particular patent application follows the analysis suggested in the "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility". Note that the text of the Guidelines is italicized.

To satisfy section 101 requirements, the claim must be for a practical application of the § 101 judicial exception, which can be identified in various ways (Guidelines, p. 19):

- The claimed invention "transforms" an article or physical object to a different state or thing.
- The claimed invention otherwise produces a useful, concrete and tangible result.

In the instant case, the claimed invention does not "transform" an article or physical object to a different state or thing because it is a method for identifying an amino acid sequence. This does not preclude the subject matter to be patentable as, for eligibility analysis, as

physical transformation "is not an invariable requirement, but merely one example of how a mathematical algorithm [or law of nature] may bring about a useful application." AT&T, 172 F.3d at 1358-59, 50 USPQ2d at 1452. If the examiner determines that the claim does not entail the transformation of an article, then the examiner shall review the claim to determine if the claim provides a practical application that produces a useful, tangible and concrete result. In determining whether the claim is for a "practical application," the focus is not on whether the steps taken to achieve a particular result are useful, tangible and concrete, but rather that the final result achieved by the claimed invention is "useful, tangible and concrete." The claim must be examined to see if it includes anything more than a § 101 judicial exception. If the claim is directed to a practical application of the § 101 judicial exception producing a result tied to the physical world that does not preempt the judicial exception, then the claim meets the statutory requirement of 35 U.S.C. § 101. If the examiner does not find such a practical application, the examiner has determined that the claim is nonstatutory. (Guidelines, p. 20)

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The question is thus whether the final result achieved by the claimed invention satisfies all three criteria of being useful, and concrete, and tangible.

Furthermore, the useful, tangible, and concrete result must be recited in the claim itself, rather than addressed in specification.

(2) **"TANGIBLE RESULT"** The tangible requirement does not necessarily mean that a claim must either be tied to a particular machine or apparatus or must operate to change articles or materials to a different state or thing. However, the tangible requirement does require that the claim must recite more than a § 101 judicial exception, in that the process claim must set forth a practical application of that § 101 judicial exception to produce a real-world result. The opposite meaning of "tangible" is "abstract."

The instant claims are drawn to computational method for identifying an amino acid sequence. However, as claimed, the method does not produce a tangible result. For example, the method as claimed may take place entirely within the confines of a computer or a human mind without any communication to the outside world and without using or making available for use, the results of the computation. In one embodiment of the invention, the identified amino acid sequence is capable of being output to a carrier wave, which per se, is not statutory. Thus, the instant methods of the claims may not produce any tangible result. This rejection may be overcome by indicating the identified amino acid sequence can be output to a user or computer memory.

Therefore, the final result achieved by the claimed invention does not satisfy all three criteria of being useful, and concrete, and tangible.

Claim Rejections - 35 USC § 103

The following rejection is reiterated from the Office action of 12 December 2006:

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ribot et al.

The claims are drawn to a method for identifying an amino acid sequence, comprising the steps of searching for putative open reading frames or protein coding sequences within a computer database containing SEQ ID NO:1 and identifying an amino acid sequence corresponding to the searched putative open reading frames or protein-coding sequences; and outputting the identified amino acid sequence.

Claim 2 further comprises searching the computer database containing SEQ ID NO:1 for an initiation codon; and searching for an in-frame termination codon downstream of the initiation codon.

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Ribot et al. disclose a method of automated DNA sequence analysis of PCR fragments using a dye terminator reaction method (page 57, lines 2-7) for identifying serogroup B amino acid sequences comprising the step of computer assisted analysis (page 57, lines 5-7) for putative open reading frames (see Figure 1 of Ribot et al. and SEQ ID NO 6 and SEQ ID NO 3 of Ribot et al.) or coding an amino acid sequence with *N. meningitidis* nucleotide sequence (SEQ ID NO: 1 of Ribot et al.). As shown in Ribot et al., SEQ ID NO: 1 of Ribot et al. comprises the initiation codon (i.e. ATG, see SEQ ID NO:1 of Ribot et al., line 1, positions 16-18), an in frame termination codon (see SEQ ID NO:1 of Ribot et al., line 1, position 1100, and 1148). Ribot et al. discloses a method for searching ORFs or protein coding sequences of *Neisseria meningitidis* (Ribot et al., pages 57-59 expands on this analysis).

However, Ribot et al. does not discuss a computerized analysis of the entire SEQ ID NO. 1 claimed in the instant application using a computer database.

Ribot et al. does show on page 32, lines 16-25, using of relevant computer systems to accomplish the goal of analysis of sequences.

Ribot et al. state:

One of skill will recognize that there are a variety of possible ways of performing the above selection steps, and that variations on the steps are appropriate. Most typically, selection steps are performed using simple computer programs to perform the selection as outlined above; however, all of the steps are optionally performed manually. One available computer program for primer selection is the MacVector program from Kodak.

The computer system and its method of use of identifying and analyzing sequences of biomolecules (i.e. SEQ ID NO 1 of the instant application) as stated in the

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instant set of claims differs from the claimed invention only in the content of the sequence used in the search. The MPEP states in 2106.01:

When nonfunctional descriptive material is recorded on some computer-readable medium, in a computer or on an electromagnetic carrier signal, it is not statutory and should be rejected under 35 U.S.C. 101. In addition, USPTO personnel should inquire whether there should be a rejection under 35 U.S.C. 102 or 103. USPTO personnel should determine whether the claimed nonfunctional descriptive material be given patentable weight. USPTO personnel must consider all claim limitations when determining patentability of an invention over the prior art. In *re Gulack*, 703 F.2d 1381, 1385, 217 USPQ 401, 403-04 (Fed. Cir. 1983). USPTO personnel may not disregard claim limitations comprised of printed matter. See *Gulack*, 703 F.2d at 1384, 217 USPQ at 403; see also *Diehr*, 450 U.S. at 191, 209 USPQ at 10. However, USPTO personnel need not give patentable weight to printed matter absent a new and unobvious functional relationship between the printed matter and the substrate. See *In re Lowry*, 32 F.3d 1579, 1583-84, 32 USPQ2d 1031, 1035 (Fed. Cir. 1994); *In re Ngai*, 367 F.3d 1336, 70 USPQ2d 1862 (Fed. Cir. 2004).

The above paragraph cites four court decisions which, when taken together, give the same message and theme regarding prior art and patentability of computerized media.

In *In re Gulack*, the CAFC ruled to give the appellant's claims patentability over the prior art because the mathematical educating device served as functional descriptive material, distinguishing it over the prior art.

As stated on page 1 of the decision:

Printed matter that is not functionally related to substrate does not distinguish invention from prior art in terms of patentability; although printed matter must be considered, in that situation it may not be entitled to patentable weight.

In *In re Ngai*, the CAFC did not give patentable weight over the prior art to an identical process of amplifying ribonucleic acids with a distinct set of printed instructions to execute this process because this set of instructions is not functional and therefore does not serve to distinguish it over the prior art.

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In *In re Lowry*, the CAFC gives functional data structures patentability, and distinguishes these data structures and computer memory from nonfunctional printed matter.

As stated on page 1 of the decision:

Claims for data processing system are neither anticipated by, nor obvious in view of, prior patent for database management system, since claimed invention, which employs plurality of attribute data objects having both hierarchical and non-hierarchical relationships, involves organization of information and its interrelationships which reference neither discloses nor suggests.

In *Diehr*, the US Supreme Court ruled analogously to the previous three cases with regards to mathematical equations. As stated at the bottom of page 10 of the ruling:

when a claim containing a mathematical formula implements or applies that formula in a structure or process which, when considered as a whole, is performing a function which the patent laws were designed to protect (e.g., transforming or reducing an article to a different state or thing), then the claim satisfied the requirements of 35 U.S.C. 101.

The difference between Ribot et al. and the claimed invention constitutes non-functional descriptive material because the content of the nucleic acid sequence database does not alter how the computer system functions, i.e., the database of the claimed computer system does not reconfigure the computer system to perform a different function than the computer system of Ribot et al. Therefore, no patentable weight is given to the content of the database on the claimed computer system and its method of use.

Response to Arguments:

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Applicant's arguments filed 9 July 2007 have been fully considered but they are not persuasive.

Applicants have arguments pertaining to each of the four court decisions cited in the previous Office action.

With regards to *In re Gulack*, applicants state:

...the Examiner fails to provide any reasons why *Gulack* supports his argument that the sequence in a database is not functional. The SEQ ID NO: 1 of the claimed invention is an important functional element that substantially alters the result of the method.

Applicants then assert that the rationale for functionality of the descriptive material is the size of the sequence (i.e. it is three orders of magnitude greater than that of the longest sequence of Ribot et al.)

This is not found to be persuasive because page 7 of the Office action states a rationale for use of this court decision:

The difference between Ribot et al. and the claimed invention constitutes non-functional descriptive material because the content of the nucleic acid sequence database does not alter how the computer system functions.

Furthermore, the mere size of the genetic sequence does not invoke functionality upon the descriptive material. In other words, the sequence length can approach infinite lengths and not have an effect on the operation of a computer system.

With regards to *In re Ngai*, applicant argues that that the sequence is not printed, not is it a set of instructions; consequently, *Ngai* is not analogous to the claimed invention.

This is not found to be persuasive, because while *Gulack* teaches that functional descriptive material should be given patentable weight, the role of *Ngai* is to teach that

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nonfunctional descriptive material should not be given patentable weight. Taken together, *Gulack* and *Ngai* reinforce the fact that instructions (or data) that do not effect the structure or function of a computer should not be given patentable weight. The fact of the data being in the form of written instructions as in *Ngai* or in the form of sequence data does not have an effect on the outcome of the legal reasoning of these two cases. The sequence data of the instant claims does NOT effect the operation of the given computer system and database.

Applicant continues to expand on how the size of the sequence causes the instant set of claims to be functional as defined in the court decision of *In re Lowry* and *In re Diehr*. While the sequence in the instant set of claims may have noteworthy and significant functionalities scientifically, the legal functionalities of the actual sequences on the relevant computerized databases are questionable at best.

Applicant next argues on pages 4-5 of the Remarks of 9 July 2007 that the claimed subject matter must be considered as a whole. This assertion by applicants is correct, and the set of claims have been examined as a whole. However, the patentable weight assigned to each embodiment of the claimed invention varies according to the principles described above.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the central PTO Fax Center. The faxing of such pages must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61

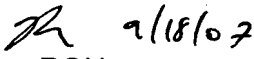
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(November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)).
The Central PTO Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Negin, Ph.D., whose telephone number is (571) 272-1083. The examiner can normally be reached on Monday-Friday from 7am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Marjorie Moran, Supervisory Patent Examiner, can be reached at (571) 272-0720.

Information regarding the status of the application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information on the PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

 2/18/07
RSN
18 September 2007

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PRIMARY EXAMINER